REMARKS

Favorable consideration of this application is respectfully requested in view of the above amendment and the following remarks.

Claims 1-6, 8, and 10-15 are pending in the application. Claims 10, 11, 14 and 15 have been withdrawn as non-elected subject matter. Claims 1-6, 8, 12 and 13 have been objected to and claims 1-5, 8 and 12 have been rejected. Claims 1-6, 8, 12 and 13 have been amended. No new matter has been added.

I. Objections to Claims 1-6, 8, 12 and 13.

Claims 1-5, 6, 8, 12 and 13 have been objected to for containing non-elected subject matter.

In response, claims 1 and 2 have been amended to delete the feature wherein R2/R7 form a ring.

Claim 6 has also been objected to. The Examiner contends that claim 6 is not written in proper Markush format in that the last and second to last compound recited in claim 6 lack the term "and".

In response, the term "and" has been inserted between the last and second to last compound recited in claim 6.

Claim 1 has also been objected to. The Examiner contends that the following two entries appear to be duplicates: "R, when present in X2 or X3, may form together with R3 a 5-8 membered ring," and "R3 together with R, when present in X2 or X3, forms a 5-8 membered ring".

In response, claim 1 has been amended to delete the phrase "R3 together with R, when present in X2 or X3, forms a 5-8 membered ring".

In view of the above, withdrawal of the objections to claims 1-6, 8, 12 and 13 is respectfully requested.

II. Rejection of Claims 1-5, 8 and 12 Under 35 U.S.C. §112, First Paragraph, For Failing to Comply With the Written Description Requirement.

Claims 1-5, 8 and 12 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that with respect to Formula I, all variables are claimed broader than what is supported by the disclosure (R3: for all claims except claim 3, R4, for all claims, R5/R5' for all claims, R6: for all claims). The Examiner also asserts that the compounds reduced to practice support the following definitions for the variables R3: H, (C1-6) alkyl; R4: H, (C1-6) alkyl; or R3 and R4 form pyrolidine or morpholine; R5/R5': H or (C1-4) alkyl; R6: H, (C1-4)alkyl. The Examiner also asserts that there is no disclosure of species (e.g., by reduction to structural/chemical formulas) in addition to those reduced to practice. The Examiner further asserts that the instant specification does not disclose a correlation between function and structure, and because such correlation is not commonly known in the art, one of ordinary skill would not know what specific structural elements would allow for preservation of activity within the unrepresented genus. The Examiner concludes (i) substantial structural variation exists in the genus/subgenus embraced by claims 1-5, 8 and 12; (ii) disclosure of species supporting genus is limited to compounds reduced to practice, which scope is not commensurate with the scope of the genus/subgenus claimed; (iii) common structural attributes of the claimed genus/subgenus, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art.

Applicants respectfully traverse the Examiner's rejection of lack of written description.

With respect to satisfying the written description requirement, the Applicant must describe the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Applicants have provided more than sufficient detail with respect to this requirement.

In this regard, more than forty examples of compounds have been disclosed as well as disclosure of *in vitro* and *in vivo* activity of these compounds as CB1 receptor agonists.

Further, in contrast to the Examiner's assertion that the compounds reduced to practice support only variables R3: H, (C1-6) alkyl; R4: H, (C1-6) alkyl,; or R3 and R4 form pyrolidine or morpholine; R5/R5'' H or (C1-4) alkyl; R6; H, (C1-4)alkyl, the specification provides other examples (i.e., reduction to practice) of R3, R4, R3/R4 ring and R6 besides the moieties listed by the Examiner. For example, R3 and R4, are shown to be methoxyethyl (see examples 2C, 6 and 8A), and hydroxyethyl (see examples 15C, 23B and 23C). Accordingly, there are representative working examples of substituted alkyls to support the substituted alkyls recited for R3 and R4. As there is sufficient support for R3 and R4 to be alkyls and substituted alkyls, it is feasible that one skilled in the art could envisage C3-C7 cycloalkyl as is recited for R3 and R4 in claim 1 and thus be in possession for all the recited moieties for R3 and R4. With respect to the Examiner's assertion that only pyrolidine and morpholine are reduced to practice for R3/R4 ring, the specification also provides examples wherein R3/R4 ring are piperidine (see Example 8C), and thiomorpholine (see Example 17E). Accordingly, there are a representative number of R3/R4 rings (including substituted rings) to support the recitation for R3/R4 found in claim 1. With respect to the Examiner's assertion that for R6 only H, or (C1-4) alkyl are reduced to practice, it is respectfully submitted that it would be feasible for one skilled in the art to envisage other moieties similar in structure or size to H or (C1-4)alkyl such as (C1-4)alkyloxy, halogen or CN that may be substituted at the R6 position as is recited for R6 in claim 1, and thus be in possession of all the moieties recited for R6. With respect to the Examiner's assertion that for

R5/R5' only H or (C1-6) alkyl are reduced to practice, it is noted that amended claim 1 recites that R5 or R5' can be H or (C1-C6) alkyl.

With respect to the Examiner's assertion pertaining to the structure/function or SAR of the presently claimed compound, it is respectfully submitted that Applicants are not required to provide SAR information or data to satisfy the written description requirement under 35 U.S.C. §112, first paragraph.

Since Applicants have provided representative examples of the aforementioned groups, and have actually reduced to practice over forty compounds, it is submitted that no further description is required to demonstrate that the inventor was in possession of the compound of claim 1.

In view of the above, withdrawal of the rejection of claims 1-5, 8 and 12 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, is respectfully requested.

III. Rejection of Claims 1-5, 8 and 12 Under 35 U.S.C. §112, First Paragraph, For Failing to Comply With the Enablement Requirement .

Claims 1-5, 8 and 12 have been rejected under 35 U.S.C. §112, first paragraph, based on an alleged lack of enablement. In particular, the Examiner asserts that the claims are drawn to compounds that do not have written support. The Examiner also asserts that while the specification discloses that the compounds are agonists of the CB1 receptor, an additional utility is neither disclosed not known in the art. The Examiner also asserts that the level of ordinary skill is high, but the level of predictability is low. The Examiner also asserts that the direction and working examples are limited to the compounds that are adequately represented by the disclosure. The Examine further asserts that it would require undue experimentation for one of ordinary skill to first test which of the compounds possess this activity before being able to practice the invention commensurate in scope with the breadth of the instant claims.

Applicants respectfully traverse the Examiner's rejection for lack of enablement.

As discussed above, the claimed compound of formula I, particularly with respect to each of the variables' substituents of formula I, is adequately described in the specification. In addition, a detailed description of methods for preparing the claimed compounds of formula I is provided on pages 5-10 and each of the examples in the specification provides a method of preparing the claimed compound of formula I.

The specification provides an *in vitro* assay for determining CB1 activity (see Example 41) as well as an animal model (Examples 42) demonstrating efficacy of a representative number of compounds falling within the scope of claim 1.

With respect to the Examiner's statement that no additional utility for these compounds other than as agonists of CB1 receptors is provided, it is well known that compounds possessing agonist activity toward the CB1 receptor have therapeutic potential in the treatment of pain as is indicated in the Tarzia et al. reference cited by the Examiner and in the present specification on page 1, line 5, and lines 19-37.

Further, with respect to the Examiner's reference to Tarzia et al. and Huffman et al. to show the unpredictability of the claimed compounds, as acknowledged by the Examiner the structures of the claimed compounds are completely different from the compounds described in the Tarzia et al. and Huffman et al. references, and thus these references say nothing about the predictability of activity with respect to the presently claimed compounds. Indeed, Applicants have provided a representative number of compounds in Table 1, from the over forty examples of disclosed compounds, that possess the requisite in *vitro* and *in vivo* activity.

For these reasons, Applicants submit that the specification provides an enabling disclosure for the claimed compounds of formula I describing synthetic methods for making the compounds as well as showing agonistic activity toward the receptor as well as *in vivo* activity in an animal model. Therefore, Applicants submit that one skilled in the art reading the disclosure

of the present application would know how to make and use the claimed invention without the need for undue experimentation.

In view of the above, withdrawal of the rejection of claims 1-5, 8 and 10 under 35 U.S.C. §112, first paragraph, based on lack of enablement of the specification, is respectfully requested.

IV. Rejection of Claim 1 Under 35 U.S.C. §112, Second Paragraph, As Being Indefinite.

Claim 1 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite in the recitation of the term "derivative" and "general". To facilitate prosecution, while not necessarily agreeing with the grounds for the rejection, claim 1 has been amended to delete the terms "derivative" and "general." Claims 2-6, 8, 12 and 13 have also been amended to delete the term "derivative" to conform with the language of claim 1.

In view of the above, withdrawal of the rejection of claim 1 under 35 U.S.C. §112, second paragraph, is respectfully requested.

V.Obviousness Double Patenting Rejection of Claims 1-5, 8 and 12 As Being Unpatentable Over Claims 1-5, 8 and 9 of Application Ser. No. 11/506,579.

Claims 1-5, 8 and 12 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8 and 9 of application ser. no. 11/506,579.

In response, Applicants request that this rejection be held in abeyance until indication by the Examiner that the pending claims are otherwise allowable.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, she is requested to call the undersigned at the number listed below.

Dated: July 11, 2008

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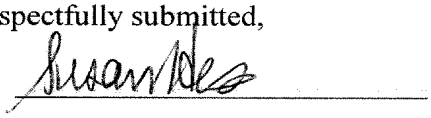
By 

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